

REMARKS

I. INTRODUCTION

Receipt of the final Office Action of May 18, 2004 is acknowledged. Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 14, 19, 23, 33, 37, 44, 49, 50 and 51 are currently being amended.

The amendments to the claims serve to clarify the action between the biological species. The term “reversibly disrupting” is recited in the claims and encompasses any form of reversible dissociation and/or denaturing and/or disruption of the biomolecular interaction contained within the matrix. Support for the claim amendment is found on page 7, line 1; page 21, lines 13-17 and original claim 44.

Claim 38 is canceled.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 14-37 and 39-65 are now pending in this application.

II. THE TELEPHONE CONFERENCE OF AUGUST 5, 2004

The undersigned appreciates the courtesies that the Examiner extended to her, one of the inventors, John Brennan, and the inventor’s Canadian counsel Anita Nador during the telephone conference of August 5, 2004. The Examiner discussed the claims and the lack of recitation of a condition to reversibly disrupt the biomolecular interaction.

III. RESTRICTION/ELECTION

Claims 14, 23, 33, 37, 44 and 49 have been amended to recite that the carrier is according to claim 50. Applicant’s request rejoinder of these claims after allowance pursuant to the Official Gazette notice dated March 26, 1996 (1184 O.G. 86) providing guidelines in

response to In re Ochiai, rejoinder of these claims (which depend from claim 50) is requested upon indication of the allowability of claim 50.

IV. THE OFFICE ACTION

The Examiner has rejected claims 50-65 under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement. Applicants respectfully traverse.

The Examiner has considered the factors of *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). The court in *Wands* relied on the factors set forth in *In re Forman*, 230 USPQ 546, 547 (Bd.Pat.App. & Int. 1986) which address what constitutes “undue experimentation.” *Id.* at 737. *Forman* recites factors to be considered in determining whether the practice of a claimed invention would require undue experimentation. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737.

However, it appears that the Examiner has failed to apply the facts of this case to the law articulated in *Wands*. More specifically, the Examiner has failed to consider description of “interaction” as found on page 10 of the specification; the recitation of “disrupted” on page 21, lines 13-17 and use of denaturants as found on page 23, lines 8-32.

It is understood from the telephone interview of August 5, 2004 that the Examiner found the claims to lack enablement because of a failure to positively recite some kind of “disrupting” factor or conditions in the claims.

1. Quantity of experimentation necessary

The first factor is the quantity of experimentation needed to make or use the invention based on the content of the disclosure. The present specification provides examples of disrupting or dissociating conditions and provides examples directed to the use of the same.

2. Amount of direction and guidance in the specification

This factor involves amount of direction provided by the inventor. Here, the inventor has provided disclosure of how to prepare the carriers and incorporate the biomolecular

interactions within the matrix and how to detect the changes of the biomolecular interaction. Moreover, there is a detailed description of the types of carriers and materials useful for preparing them and types of biomolecular interactions which can be incorporated into the matrix and how such interactions can be manipulated by using disrupting or denaturing factors. Furthermore, methods and means for detection of the biomolecular interactions has been described and provided by the inventor.

3. Presence or absence of working examples

The presence of working examples is the third prong and the present specification provides examples of how to make and use the presently claimed invention.

The present specification provides examples 1-16 which describe preparation of the carriers, incorporation of the biomolecular interactions, detection of the interactions and use of the same for screening methods and for treatment methods.

4. Nature of the invention

The nature of the present invention relates to carrier substances which can have trapped within their matrix one or more biomolecular interactions which can be used for screening active substances to determine biological activity and can identify modulators of the interactions.

5. State of the prior art

The state of the prior art describes that interacting protein domains are inherently difficult to assay. Heretofore, disruption of a particular biomolecular interaction could not be detected where the results of such a test can be used to determine modulators of the interaction which can be used to develop protocols for treatment of diseases and disorders.

6. Relative skill of those in the art

The relative skill in the art relates to routine practices of the skilled worker. In the present field, the skilled worker upon reading the present patent application would be able to prepare the carriers and incorporate the biomolecular interactions within the matrix and be able to effect and/or monitor the disruption, if any of the interaction, and a possible subsequent reformation.

7. The predictability or unpredictability of the art

The level of predictability in the art is another factor to consider. Based on the difficulty of those in the past to analyze and identify interacting protein domains, the predictability of the art is uncertain. However, there has been increasing discoveries of new protein-protein interactions.

8. Breadth of the claims

The seventh factor is the breadth of the claims. The Examiner appears to assert that the use of a reversible disrupting factor is enabled. The Examiner has indicated that reciting that the biomolecular interactions of the carrier can be reversibly disrupted under disrupting conditions was enabled. Applicants have provided the phrase “under reversibly disrupting conditions” to claim 50.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

V. CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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